

REMARKS

I. Allowable Subject Matter

The Examiner's indication of the conditional allowability of Claims 11, 16, 17, 23-25 if rewritten in independent form including all of the limitations of the base claim and any intervening claims is acknowledged with appreciation. In response, Applicant has amended: Claim 11 to include the limitation of Claims 1; Claim 16 to include the limitations of Claims 14 and 15; Claim 23 to include the limitations of Claim 14; Claim 24 to include the limitations of Claim 14; and Claim 25 to include the limitations of Claim 14. Claim 17, which depends upon amended Claim 16 is also allowable. Accordingly, the allowance of Claims 11, 16, 17, and 23-25 is earnestly solicited.

II. Claim Objections

The Examiner objected to Claim 28 on the grounds that the word "combination" is misspelled. Applicant has canceled Claim 28. Examiner's objection should therefore be obviated.

III. Claim Rejections Based on 35 U.S.C. §102(b)

The Examiner has rejected Claims 1-2, 4-7, 9-10, 12-15, 18-19, 28, 30-31, and 33 under 35 U.S.C. §102(b) as being anticipated

by Lawrence et al. (U.S. 6,394,996). Applicant has cancelled claims 1-2, 4-7, 9-10, 12-13, 28, 30-31 and 33. Examiner's objections with respect to these claims should therefore be obviated.

With respect to independent Claim 14, upon which Claims 15 and 18-19 depend, Applicant respectfully disagrees that Claim 14 is anticipated by Lawrence et al. because Lawrence et al. fails to teach each and every element claimed by the Applicant. Lawrence et al. teaches a method for aspirating and irrigating tract wounds, not subdural hematomas. This difference is critical, since the use of a tract wound irrigation device, such as Lawrence's would be fatal to a patient being treated for a subdural hematoma.

Applicant is a board certified neurosurgeon who has been in practice since 2000. See Declaration under 37 CFR §1.132 of Dan Lieberman, M.D., submitted herewith and incorporated herein by reference. His practice includes the management of hundreds of patients with subdural hematomas. *Id.* Based on all of Applicant's expertise and experience in the field of neurosurgery generally and subdural hematomas specifically, the use of the irrigation and suction devices and methods disclosed in Lawrence et al. and Palestrant (U.S. 5,002,528) would create pressure in the subdural space that would be fatal to the patient. *Id.*

Because Claim 14 specifies that the method for treating subdural hematomas requires that the dual lumen catheter be inserted into a "subdural space" this element must be found in the Lawrence et al. reference in order for Lawrence et al. to be considered a proper reference under 35 U.S.C. §102. There is not a single reference to "subdural" or the "subdural space" in Lawrence et al. Because Lawrence et al. fails to teach each and every aspect claimed by the Applicant, this rejection should be obviated.

Therefore, Applicant believes that Claim 14, upon which Claims 15 and 18-19 depend, is not anticipated by the Lawrence et al. reference.

IV. Claim Rejections Based on 35 U.S.C. §103

The Examiner has rejected Claims 3 and 8 under 35 U.S.C. §103(a) as being unpatentable over Lawrence et al. (U.S. 6,394,996). The Examiner has also rejected Claims 6-7, 20-21, 26-27, 29 and 32 under 35 U.S.C. §103(a) as being unpatentable over Lawrence et al. in view of Palestrant (U.S. 5,002,528). The Examiner has also rejected Claim 22 under 35 U.S.C. §103(a) as being unpatentable over Lawrence et al. in view of Boss et al. (U.S. 5,411,883).

Applicant has cancelled Claims 3, 6-8, 29 and 32.
Examiner's objections with respect to these claims should
therefore be obviated.

With respect to Claim 14, Applicant respectfully disagrees
that Claim 14 is anticipated or obvious in light of the cited
references. Because Claims 20-22 and 26-27 depend upon Claim
14, Applicant also believes that these claims are not obvious in
light of Lawrence et al. in view of Palestrant and/or Boss et
al..

None of the cited references of Lawrence et al., Palestrant
or Boss et al. make the suggestion to insert a dual-lumen
catheter into a subdural space. In fact, none of the references
include the words "subdural" or "subdural space" anywhere in the
patents. As discussed above, the pressure created by the
suction and irrigation for treating tract wounds described in
the Lawrence et al. and Palestrant patents would be fatal to the
brain. See Declaration under 37 CFR §1.132 of Dan Lieberman,
M.D., submitted herewith and incorporated herein by reference.

In order for the combination of references cited by the
Examiner, singly or in combination, to satisfy the obviousness
requirement, the prior art references must suggest the
desirability of the combination. The mere fact that the
references may be combined or modified does not in itself render
the resultant combination obvious. In re Mills, 916 F.2d 680

(Fed. Cir. 1990). Furthermore, the level of skill in the art cannot be relied upon to provide the suggestion to combine references. Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308 (Fed. Cir. 1999).

It is therefore not sufficient that the Lawrence et al. or Palestrant devices could be inserted into the subdural space, there must also be a suggestion in these references to the desirability of the use of irrigation and suction in the subdural space. Lawrence et al. suggests a preferred irrigation pressure of 15 p.s.i., "that being the generally accepted standard maximum stagnation pressure for wound treatment." See Column 4, Lines 27-30. Pressure of this magnitude in the subdural space would be fatal in the brain. See Declaration under 37 CFR §1.132 of Dan Lieberman, M.D., submitted herewith and incorporated herein by reference.

Palestrant discloses "cavities to be drained are typically situated in an intra-abdominal, retroperitoneal, pelvic or plural location." See Column 4, Lines 15-17. There is no suggestion in Palestrant to irrigate and drain the subdural space with a dual-lumen catheter. Furthermore, Palestrant specifically recommends high pressure irrigation, the kind that would be fatal in the subdural space when stating: "The irrigant should be injected rapidly in order to clear debris such as necrotic material or

blood clots from catheter drainage holes 37." See Column 4, Lines 42-44.

Because none of the cited references of Lawrence et al., Palestrant or Boss et al. make the suggestion to insert a dual-lumen catheter into a subdural space, these rejections should now be obviated.

VI. Conclusion

Applicant respectfully submits that this Amendment Letter, in view of the Remarks offered herein, is fully responsive to all aspects of the objections and rejections tendered by the examiner in the Office Action. None of the cited prior art, nor any combination thereof, discloses a method for treating subdural hematomas that includes the inserting of a dual lumen catheter into a subdural space. For all the foregoing reasons, the Applicant respectfully asserts that all claims are patentable over the cited prior art and respectfully requests that these Claims be allowed.

It is not believed that this Amendment Letter requires any additional fees, but if there are any fees incurred by this communication, please deduct them from our Deposit Account NO. 23-0830.

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Respectfully submitted,



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